DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 29, 2014

MEDCOMP®
Mr. Jonathan Schell
Regulatory Associate
1499 Delp Drive
Harleysville, PA 19438

Re: K141633
Trade/Device Name: Medcomp® Pro-PICC® with Valve Technology
Regulation Number: 21 CFR 880.5970
Regulation Name: Catheter, Intravascular, Therapeutic, Long-Term
Regulatory Class: II
Product Code: LJS
Dated: June 19, 2014
Received: June 20, 2014

Dear Mr. Schell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141633

Device Name

Pro-PICC with Valve Technology

Indications for Use *(Describe)*

The Pro-PICC catheter with valve technology is indicated for short and long peripheral access to the central venous system for intravenous therapy and power injection media, and allow for central venous pressure monitoring. For blood sampling, infusion, or therapies, use a 4F or larger catheter. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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Section 5 510(k) SUMMARY Traditional 510K

A. **Submitter Information:**

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201, x2271 Fax: (215) 256-9191
Contact:	Jonathan Schell Regulatory Associate
Date Prepared:	06/16/2014

B. **Trade Name:** Medcomp® Pro-PICC®CT with Valve Technology

Common Name:	Catheter, Intravascular, Therapeutic, Long-Term
Classification Name:	Long Term Intravascular Catheter (80 LJS)
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
C.F.R. Section:	880.5970
Class:	II

C. **Predicate Devices:**

K091953 Medcomp, Pro-PICC® CT, class II 880.5970
K092347 Medcomp, Pro-PICC® CT, class II 880.5970
K072230 Bard Access Systems, Inc., PowerPICC SOLO™, class II 880.5970

D. **Device Description:**

The Pro-PICC®CT with Valve Technology is an open-ended lumen catheter designed for power injection. The catheters are an extension of the Medcomp® Pro-PICC®CT (K091953 and K092347). The Pro-PICC®CT with Valve Technology is comprised of a soft radiopaque polyurethane material. The lumen has a reverse taper design and is connected to the extensions via a soft pliable hub with suture wing for secure placement. The catheter lumen terminates through an extension to a female luer-lock connector. Assembled within each luer is a Bi-directional valve that can control fluid flow in two directions. The valve is normally closed but opens when flow is induced in either direction. Each extension is marked with the lumen gauge size, "Valved CT Catheter" or "Do Not Power Inject", and the maximum flow rates. The transition between lumen and extension is housed within a molded hub. The hub is marked with the catheter French size. The outside diameter of the lumen increases gradually near the hub to aid in kink resistance and to provide a mechanical obstruction to bleeding from the venotomy. The lumen is marked with depth marks every centimeter.

The Pro-PICC®CT with Valve Technology catheter is available in additional French sizes and either a single, double, or triple lumen. The catheter has a usable length of

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50cm to 60cm depending on French size with depth markings in 5cm increments. Stylet and adaptor sideport are provided to assist in catheter insertion.

The catheter is packaged sterile in a variety of tray configurations with the necessary accessories to facilitate catheter insertion.

E. **Indications for Use:**

The PRO-PICC®CT catheter with valve technology is indicated for short or long term peripheral access to the central venous system for intravenous therapy and power injection of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapies, use a 4F or larger catheter. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.

F. **Comparison to Predicate Devices:**

The PRO-PICC®CT with valve technology catheter is substantially equivalent to the predicate devices in terms of intended use, anatomical location, basic design, materials, performance, labeling, manufacturing process and method of sterilization.

The difference between the PRO-PICC®CT with valve technology and the Medcomp Pro-PICC®CT (K091953 and K092347) predicate devices is the addition of the valve technology to the luer.

G. **Bench / Performance Data:**

Performance testing of the proposed device was conducted in accordance with applicable international standards and FDA guidance documents. Performance standards for pressure injection have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act. Testing is based upon internal engineering testing methods.

The results of these tests in conjunction with the substantial equivalence claims effectively demonstrate the proposed devices are equivalent to the predicate devices.

H. **Biocompatibility:**

Testing for all materials used for the PRO-PICC®CT with valve technology has been done on the complete, finished PRO-PICC®CT device. All biocompatibility testing demonstrates the materials used meet the requirements of ISO 10993, and is contained in section 15.

I. **Technological Characteristics:**

Technological similarities between the proposed device and predicate devices remain the same.

J. **Summary of Substantial Equivalence:**

The proposed device meets the performance criteria of design verification as specified by ISO standards, guidance documents and internal test protocols. The

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proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed device is substantially equivalent to the legally marketed predicate device.